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09/914,380	01/04/2002	Thadeu Rezende Provenza	71370-0001	3774

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EXAMINER

SAADAT, CAMERON

ART UNIT

PAPER NUMBER

3713

DATE MAILED: 02/04/2004

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/914,380

Applicant(s)

PROVENZA, THADEU REZENDE

Examiner

Cameron Saadat

Art Unit

3713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-25 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 6-16, 18-23 and 25 is/are rejected.  
7) ☒ Claim(s) 17 and 24 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

In response to amendment filed 11/21/03 newly added claims 6-25 are pending in this application. Claims 1-5 have been cancelled. The substitute specification filed 11-21-03 has not been entered for introducing new matter into the disclosure of the invention.

***Specification***

The substitute specification filed 11/21/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material: "wherein the peripheral edge of the cover *sealingly* engages the peripheral edge of the base" is not supported by the original disclosure. Applicant is required to cancel the new matter in the reply to this Office Action or indicate further support in the original disclosure.

***Claim Rejections - 35 USC § 112***

Claims 6-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain the phrase "wherein said peripheral edge of said cover *sealingly* engages said peripheral edge of said base" which was not described in the original disclosure in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 6-16, 18-19, 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (USPN 4,867,686) in view of Barrie et al. (USPN 5,803,746; hereinafter Barrie).**

Regarding claim 6, Goldstein discloses a body comprising: a filler material 18 for simulating human female breast tissue; a base 14 comprising a peripheral edge and an upper surface for supporting the filler material 18; a cover 12 comprising a peripheral edge and a first surface; and at least one pathological simulator element 20 disposed within the filler material 18, wherein the peripheral edge of the cover is attached to the peripheral edge of the base to contain the filler material between the cover and the base. Goldstein discloses all of the claimed subject matter with the exception of explicitly disclosing that the base is *substantially rigid*. However, Barrie discloses simulated breast tissue that is mounted on a plate 26. Hence, in view of Barrie, it would have been obvious to an artisan to modify the base described in Goldstein by providing a *rigid* base to further support the breast model and provide a backing that would be strong enough to withstand repeated pressures exerted on the breast model (see Goldstein, Col. 3, lines 63-67).

Regarding claim 19, Goldstein discloses a body comprising: a filler material 18 for simulating human female breast tissue; a base 14 comprising a peripheral edge and an upper

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surface for supporting the filler material 18; a cover 12 comprising a peripheral edge and a first surface; and at least one pathological simulator element 20 disposed within the filler material 18. Goldstein discloses all of the claimed subject matter with the exception of explicitly disclosing a *frame*. However, Barrie discloses simulated breast tissue that is mounted on plate 26 and supported by frame 24, which creates a recess for supporting the base 12. In view of Barrie, it would have been obvious to an artisan to modify the base described in Goldstein by providing a *frame* to further support the breast model by surrounding the sides of the resilient body and base.

Regarding claim 25, Goldstein discloses a body comprising: a filler material 18 for simulating human female breast tissue; a base 14 comprising a peripheral edge and an upper surface for supporting the filler material 18; a cover 12 comprising a peripheral edge and a first surface; at least one pathological simulator element 20 disposed within the filler material 18, wherein the peripheral edge of the cover is attached to the peripheral edge of the base to contain the filler material between the cover and the base. Goldstein discloses all of the claimed subject matter with the exception of explicitly disclosing a rib disposed within the filler material. However, Barrie discloses a breast model, training device comprising ribs 38. In view of Barrie, it would have been obvious to one of ordinary skill in the art to modify the filler material described in Goldstein by providing simulated ribs in the filler material in order to enhance the simulation of a human body, and thereby providing a more realistic training model.

Regarding claims 7 and 21, Goldstein discloses a body wherein the pathological simulator element 20 is fixed and secured to the base (see Fig. 2).

Regarding claims 8 and 21, Goldstein discloses a body wherein the pathological simulator element 20 is floating and suspended within the filler material (see Fig. 1).

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Regarding claim 9, Goldstein discloses a body wherein the floating pathological simulator element comprises an irregular shape or spherical shape (Col. 3, lines 40-43).

Regarding claim 10, Goldstein discloses a body wherein the floating pathological simulator element is encased in an elastic or flexible casing (Col. 3, lines 43-45).

Regarding claim 11, Goldstein discloses a body wherein the floating pathological simulator element comprises nylon (Col. 3, line 42).

Regarding claim 12, Goldstein discloses a body wherein the base 14 comprises a man-made material.

Regarding claim 13, Goldstein discloses a body wherein the base comprises a circular shape (See Fig. 1).

Regarding claim 14, Goldstein discloses a body wherein the cover comprises silicon (Col. 2, line 66 – Col. 3, line 1).

Regarding claim 15, Goldstein discloses a body comprising a pigmented areola and quadrants (Col. 6, lines 35-40; Col. 2, lines 49-51; Col. 4, line 41).

Regarding claim 16, Goldstein discloses a body wherein inked markings or different pigmentations may be used to identify quadrants of the model (Col. 6, lines 59-63).

Regarding claim 18, Goldstein discloses a body wherein the cover 12 further comprises a second surface 30 comprising a variety of tones that correspond to human skin color.

Regarding claims 22 and 23, Goldstein discloses all of the claimed subject matter with the exception of explicitly disclosing a rib disposed within the filler material. However, Barrie discloses a breast model, training device comprising ribs 38. In view of Barrie, it would have been obvious to one of ordinary skill in the art to modify the filler material described in

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Goldstein by providing simulated ribs in the filler material in order to enhance the simulation of a human body, and thereby providing a more realistic training model.

**Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein (USPN 4,867,686) in view of Barrie et al. (USPN 5,803,746), further in view of VanWinkle (USPN 5,913,686).**

The combination of Goldstein and Barrie discloses all of the claimed subject matter except for those directed towards providing a base comprising information of public interest and publicity. However, VanWinkle teaches a breast model wherein information of public interest is provided on the base. In view of VanWinkle, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the breast training model described in the combination of Goldstein and Barrie, by providing information of public interest, in order to provide informative and instructional information utilized in conjunction with the breast model and thereby enhancing training.

***Response to Arguments***

Applicant's arguments with respect to claims 6-25 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

Claims 17 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance:

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Patentability is seen in, although not limited to: dependent claims 17 and 24, the combination of a simulation of a human, female breast tissue comprising a cover having five regions, the regions comprising a pigmented areola and nipple region and four quadrant regions of the glandular area; and wherein the pigmented areola and nipple region comprises three aleatoric points, each point comprising a different color which corresponds to a secretion type that may be emerged by palpation. The closest prior art of record does not teach or fairly suggest this feature in the combination.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is 703-305-5490. The examiner can normally be reached on M-F 8:00 - 5:00.



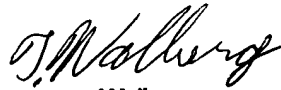
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Teresa J Walberg can be reached on 703-308-1327. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



CS



**Teresa Walberg**  
**Supervisory Patent Examiner**  
**Group 3700**